



Clinical trial results:

A Comparison of LY2605541 Versus Insulin Glargine as Basal Insulin Treatment in Combination With Oral Anti-Hyperglycemia Medications in Insulin-Naive Patients With Type 2 Diabetes Mellitus: A Double-Blind, Randomized Study .

Summary

EudraCT number	2011-000842-39
Trial protocol	HU SK GB CZ DE LT ES GR FI IT
Global end of trial date	16 January 2014

Results information

Result version number	v1 (current)
This version publication date	02 April 2018
First version publication date	02 April 2018

Trial information

Trial identification

Sponsor protocol code	I2R-MC-BIAJ
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01435616
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12141

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 January 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	16 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to demonstrate that LY2605541 is noninferior to insulin glargine for the change in HbA1c from baseline to 52 weeks of treatment in insulin naive patients with Type 2 Diabetes Mellitus (T2DM).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 559
Country: Number of subjects enrolled	Turkey: 11
Country: Number of subjects enrolled	Israel: 24
Country: Number of subjects enrolled	Russian Federation: 50
Country: Number of subjects enrolled	Mexico: 40
Country: Number of subjects enrolled	Puerto Rico: 58
Country: Number of subjects enrolled	Canada: 27
Country: Number of subjects enrolled	Argentina: 101
Country: Number of subjects enrolled	Brazil: 30
Country: Number of subjects enrolled	Romania: 62
Country: Number of subjects enrolled	Australia: 45
Country: Number of subjects enrolled	South Africa: 15
Country: Number of subjects enrolled	New Zealand: 19
Country: Number of subjects enrolled	Poland: 99
Country: Number of subjects enrolled	Slovakia: 22
Country: Number of subjects enrolled	Spain: 53
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	Czech Republic: 13
Country: Number of subjects enrolled	Finland: 13

Country: Number of subjects enrolled	Germany: 99
Country: Number of subjects enrolled	Greece: 30
Country: Number of subjects enrolled	Hungary: 102
Country: Number of subjects enrolled	Italy: 37
Country: Number of subjects enrolled	Lithuania: 12
Worldwide total number of subjects	1538
EEA total number of subjects	559

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1066
From 65 to 84 years	469
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

No text entered

Pre-assignment

Screening details:

No text entered

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	LY2605541

Arm description:

LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks

Arm type	Experimental
Investigational medicinal product name	LY2605541
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks.

Arm title	Glargine
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Arm description:

Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.

Arm type	Active comparator
Investigational medicinal product name	Glargine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.

Number of subjects in period 1	LY2605541	Glargine
Started	1003	535
Received at Least 1 Dose of Study Drug	1003	535
Completed	832	455
Not completed	171	80
Adverse event, serious fatal	7	2
Consent withdrawn by subject	66	24
Physician decision	20	7
Adverse event, non-fatal	39	21
Sponsor Decision	1	-
Lost to follow-up	22	13
Protocol deviation	16	13

Baseline characteristics

Reporting groups

Reporting group title	LY2605541
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Reporting group description:

LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks

Reporting group title	Glargine
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Reporting group description:

Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.

Reporting group values	LY2605541	Glargine	Total
Number of subjects	1003	535	1538
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	58.80	59.35	
standard deviation	± 9.86	± 9.80	-
Gender categorical			
Units: Subjects			
Female	453	227	680
Male	550	308	858
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	201	96	297
Not Hispanic or Latino	648	355	1003
Unknown or Not Reported	154	84	238
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	24	15	39
Asian	25	12	37
Native Hawaiian or Other Pacific Islander	3	2	5
Black or African American	68	34	102
White	875	469	1344
More than one race	8	3	11
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	LY2605541
Reporting group description: LY2605541 titrated based on blood glucose readings, administered subcutaneously (SC), once daily in combination with at least 2 pre-study oral antihyperglycemic medications (OAMs) prescribed by the personal physician, for 52 or 78 weeks	
Reporting group title	Glargine
Reporting group description: Glargine titrated based on blood glucose readings, administered SC, once daily in combination with at least 2 pre-study OAMs prescribed by the personal physician, for 52 or 78 weeks.	

Primary: Change From Baseline to 52 Week Endpoint in Hemoglobin A1c (HbA1c)

End point title	Change From Baseline to 52 Week Endpoint in Hemoglobin A1c (HbA1c)
End point description: HbA1c is a test that measures a person's average blood glucose level over the past 2 to 3 months. Least Squares (LS) means were calculated using a mixed model repeated measures (MMRM) with baseline HbA1c measurement, stratification factors (country, low density lipoprotein-cholesterol [LDL-C, < 100 milligrams per deciliter {mg/dL} and ≥ 100 mg/dL] and sulfonylurea [SU]/meglitinide use), visit, treatment, and visit-by-treatment interaction as fixed effects.	
End point type	Primary
End point timeframe: Baseline, 52 weeks	
Analysis Population Description: All participants who were randomized, had at least 1 dose of study medication, and at least 1 post-baseline HbA1c measurement.	

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of HbA1c				
least squares mean (standard error)	-1.55 (± 0.03)	-1.25 (± 0.04)		

Statistical analyses

Statistical analysis title	HbA1c Statistical Analysis
Comparison groups	LY2605541 v Glargine
Number of subjects included in analysis	1512
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.001
Method	Mixed Model Repeated Measures (MMRM)
Parameter estimate	LS Mean Difference
Point estimate	-0.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.19

Secondary: Rate of Total and Nocturnal Hypoglycemia Events

End point title	Rate of Total and Nocturnal Hypoglycemia Events
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End point description:

Hypoglycemia is a condition that occurs when a person's blood glucose level is lower than the normal range (less than or equal to 70 milligrams per deciliter [mg/dL] or less than 3.9 millimoles per liter [mmol/L]). Total hypoglycemia refers to an event that meets the criteria for documented symptomatic hypoglycemia, asymptomatic hypoglycemia, probable symptomatic hypoglycemia, unspecified hypoglycemia, or severe hypoglycemia. Nocturnal hypoglycemia refers to any total hypoglycemic event that occurs between bedtime and waking. Group mean (listed as LS means below) rates of total and nocturnal hypoglycemia were calculated using a negative binomial regression model (number of episodes = treatment + SU/meglitinide use + baseline hypoglycemia event rate, with log [exposure per 30 days] as the offset variable in the model).

End point type	Secondary
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End point timeframe:

Baseline to 52 weeks

Analysis Population Description: All participants who were randomized, who received at least 1 dose of study drug, and had evaluable total and/or nocturnal event data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1001	535		
Units: episodes/participant/30 days				
least squares mean (standard error)				
Rate of total hypoglycemia events	1.16 (± 0.06)	1.21 (± 0.07)		
Rate of nocturnal hypoglycemia events	0.30 (± 0.05)	0.40 (± 0.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Hemoglobin A1c Equal or Less Than 6.5% and Less Than 7.0 %

End point title	Percentage of Participants With Hemoglobin A1c Equal or Less Than 6.5% and Less Than 7.0 %
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End point description:

The percentage of participants was calculated by dividing the number of participants reaching target HbA1c by the total number of participants analyzed, multiplied by 100.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline HbA1c measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of participants				
number (not applicable)				
HbA1c ≤ 6.5%	36.1	23.9		
HbA1c < 7.0%	57.6	42.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Fasting Serum Glucose (By Laboratory Measurement)

End point title	Fasting Serum Glucose (By Laboratory Measurement)
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End point description:

LS means were calculated using a MMRM with baseline fasting serum glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable fasting serum glucose data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	521		
Units: mg/dL				
least squares mean (standard error)	114.93 (\pm 1.24)	120.13 (\pm 1.70)		

Statistical analyses

No statistical analyses for this end point

Secondary: Fasting Blood Glucose (By Participant Self-monitored Blood Glucose Readings)

End point title	Fasting Blood Glucose (By Participant Self-monitored Blood
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End point description:

LS means were calculated using a MMRM with baseline fasting blood glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable fasting blood glucose data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	994	528		
Units: mg/dL				
least squares mean (standard error)	112.57 (\pm 0.82)	112.00 (\pm 1.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: 6 Point Self-monitored Blood Glucose (SMBG)

End point title	6 Point Self-monitored Blood Glucose (SMBG)
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End point description:

Six-point SMBG profiles were obtained at pre-morning meal (fasting), pre-midday meal (lunch), pre-evening meal (dinner), bedtime, approximately 0300 hours, and pre-morning meal (fasting) the next day. Six-point SMBG profiles were obtained over 2 nonconsecutive days within the week prior to the next office visit. LS means were calculated using a MMRM with baseline blood glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable SMBG data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	943	499		
Units: mg/dL				
least squares mean (standard error)				
Pre-morning meal (n=943, n=499)	112.81 (\pm 0.96)	112.26 (\pm 1.31)		

Pre-midday meal (n=925, n=494)	127.65 (\pm 1.36)	134.52 (\pm 1.86)		
Pre-evening meal (n=928, n=494)	133.94 (\pm 1.40)	142.58 (\pm 1.91)		
Bedtime (n=911, n=486)	151.37 (\pm 1.54)	155.19 (\pm 2.10)		
0300 hours (n=909, n=466)	120.35 (\pm 1.21)	118.37 (\pm 1.67)		
Pre-morning meal (next day)(n=939, n=494)	111.11 (\pm 0.89)	109.19 (\pm 1.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Weeks in Body Weight

End point title	Change From Baseline to 52 Weeks in Body Weight
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End point description:

LS means were calculated using a MMRM with baseline body weight measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

Analysis Population Description: All participants who were randomized, who received at least 1 dose of study drug, and had evaluable body weight data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	985	522		
Units: kilograms (kg)				
least squares mean (standard error)	2.06 (\pm 0.15)	2.57 (\pm 0.21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Hemoglobin A1c

End point title	Hemoglobin A1c
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End point description:

HbA1c is a test that measures a person's average blood glucose level over the past 2 to 3 months. LS means were calculated using a MMRM with baseline HbA1C measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline HbA1c measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of HbA1c				
least squares mean (standard error)	6.91 (\pm 0.03)	7.21 (\pm 0.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin Dose Per Body Weight

End point title	Insulin Dose Per Body Weight
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End point description:

LS means were calculated using a MMRM with baseline insulin dose measurement, stratification factors (country, HbA1c, LDL-C [$<$ 100 mg/dL and \geq 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable insulin dose data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1001	532		
Units: units of insulin/kg body weight				
least squares mean (standard error)	0.45 (\pm 0.01)	0.42 (\pm 0.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Insulin Dose Adjustments to Steady-State

End point title	Number of Insulin Dose Adjustments to Steady-State
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End point description:

Insulin doses were adjusted according to an algorithm (adapted from Riddle et al. 2003) during the first

26 weeks of the study and thereafter according to investigator judgment. Steady-state was defined as the first local maximum dose (maximum of moving 4-week interval) of LY2605541 or glargine within the window of +/- 2 weeks. The number of dose adjustments to steady-state was the total number of dose changes until steady-state was reached. LS means were calculated using a MMRM with baseline insulin dose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

Baseline to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable post-baseline insulin data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1002	532		
Units: number of insulin dose adjustments				
least squares mean (standard error)	5.83 (± 0.12)	5.25 (± 0.16)		

Statistical analyses

No statistical analyses for this end point

Secondary: European Quality of Life-5 Dimension (EQ-5D)

End point title	European Quality of Life-5 Dimension (EQ-5D)
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End point description:

The EQ-5D is a generic, multidimensional, health-related, quality-of-life instrument. The profile allows participants to rate their health state in 5 health domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) using a 3-level scale of 1 to 3 (no problem, some problems, and extreme problems). These combinations of attributes are converted into a weighted health-state Index Score according to the United States population-based algorithm. Scores range from -0.11 to 1.0, where a score of 1.0 indicates perfect health. LS means were calculated using a MMRM with baseline stratification factors (country, HbA1c, and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable EQ-5D data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	892	474		
Units: units on a scale				
least squares mean (standard error)	0.88 (± 0.00)	0.88 (± 0.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin Treatment Satisfaction Questionnaire

End point title	Insulin Treatment Satisfaction Questionnaire
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End point description:

The Insulin Treatment Satisfaction Questionnaire (ITSQ) is a validated instrument containing 22 items that assess treatment satisfaction for participants with diabetes who are receiving insulin. The questionnaire measures satisfaction from the following 5 domains: inconvenience of regimen, lifestyle flexibility, glycemic control, hypoglycemic control, and insulin delivery device. Data presented are the transformed total score on a scale of 0 to 100, where higher scores indicate better treatment satisfaction. LS means were calculated using a MMRM with stratification factors (country, HbA1c, and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

Up to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable ITSQ data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	966	515		
Units: Insulin Treatment Satisfaction Questionn				
least squares mean (standard error)	84.73 (± 0.44)	85.04 (± 0.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adult Low Blood Sugar Survey

End point title	Adult Low Blood Sugar Survey
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End point description:

The adult Low Blood Sugar Survey (LBSS) is a validated, participant-reported 33-item questionnaire with items rated on a 5-point Likert scale, where 0 = never and 4 = always. The LBSS measures behaviors to avoid hypoglycemia and its negative consequences (15 items) and worries about hypoglycemia and its negative consequences (18 items). Total score is the sum of all items (range of 0 to 132). Higher total scores reflect greater fear of hypoglycemia. LS means were calculated using an analysis of covariance model (ANCOVA) with baseline LBSS score, stratification factors (country, HbA1c, and SU/meglitinide use), and treatment as fixed effects.

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable LBSS data. Missing endpoints were imputed with the last observation carried

forward (LOCF) method, using only post-baseline data.

End point type	Secondary
End point timeframe:	
Up to 52 weeks	

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	899	478		
Units: Adult Low Blood Sugar Survey				
least squares mean (standard error)	15.09 (\pm 0.49)	14.59 (\pm 0.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 52 Weeks in Triglycerides, Low Density Lipoprotein Cholesterol (LDL-C), and High Density Lipoprotein Cholesterol (HDL-C)

End point title	Change From Baseline to 52 Weeks in Triglycerides, Low Density Lipoprotein Cholesterol (LDL-C), and High Density Lipoprotein Cholesterol (HDL-C)
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End point description:

LS means were calculated using a MMRM with baseline lipid measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline lipid measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	992	528		
Units: milligrams per deciliter (mg/dL)				
least squares mean (standard error)				
Triglycerides (n=992, n=528)	10.60 (\pm 2.46)	-7.33 (\pm 3.38)		
LDL-C (n=992, n=527)	1.44 (\pm 0.83)	1.76 (\pm 1.14)		
HDL-C (n=992, n=528)	-1.91 (\pm 0.21)	-1.82 (\pm 0.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Equal or Above 2-, and 3-fold Upper Limits of Normal (ULN) for Total Bilirubin

End point title	Percentage of Participants With Equal or Above 2-, and 3-fold Upper Limits of Normal (ULN) for Total Bilirubin
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End point description:

End point type	Secondary
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End point timeframe:

Up to 52 weeks

Analysis Population Description: All participants who were randomized, had at least 1 dose of study drug, and had at least 1 post-baseline total bilirubin measurement.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	994	529		
Units: Percentage of Participants With Equal or				
number (not applicable)				
≥2-fold ULN	0.2	0.0		
≥3-fold ULN	0.1	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Treatment-Emergent Anti-LY2065541 Antibody Response (TEAR)

End point title	Overall Treatment-Emergent Anti-LY2065541 Antibody Response (TEAR)
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End point description:

The percentage of participants with a TEAR is summarized. TEAR is defined as a change in the anti-LY2605541 antibody level from undetectable at baseline to detectable at baseline, or, for those participants with detectable antibodies at baseline, change to a value with at least a 130% relative increase from baseline. Overall TEAR is defined as one or more TEAR during the specified period.

End point type	Secondary
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End point timeframe:

Baseline to 78 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable TEAR data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	988	521		
Units: percentage of participants				
number (not applicable)	43.0	37.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-participant Variability of the Fasting Blood Glucose (FBG)

End point title	Intra-participant Variability of the Fasting Blood Glucose (FBG)
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End point description:

Intra-participant variability of FBG, which was measured by SMBG, was assessed by the standard deviation of the FBG measurement at the Week 52 visit. LS means were calculated using a MMRM with baseline fasting blood glucose measurement, stratification factors (country, HbA1c, LDL-C [< 100 mg/dL and ≥ 100 mg/dL], and SU/meglitinide use), treatment, visit, and treatment-by-visit interaction as fixed effects.

End point type	Secondary
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End point timeframe:

52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable post-baseline FBG data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	991	522		
Units: mg/dL				
least squares mean (standard error)	15.56 (± 0.38)	17.08 (± 0.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Total and Nocturnal Hypoglycemic Events

End point title	Percentage of Participants With Total and Nocturnal Hypoglycemic Events
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End point description:

A hypoglycemic event is defined by a blood glucose value ≤ 70 mg/dL (3.9mmol/L). Total hypoglycemic events include documented symptomatic hypoglycemia, asymptomatic hypoglycemia, probable symptomatic hypoglycemia, unspecified hypoglycemia, or severe hypoglycemia. Nocturnal hypoglycemic events refer to any total hypoglycemic event that occurs between bedtime and waking. The percentage of participants was calculated by dividing the number of participants with hypoglycemic or nocturnal hypoglycemic events by the total number of participants analyzed, multiplied by 100.

End point type	Secondary
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End point timeframe:

Baseline to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable hypoglycemia event data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1001	535		
Units: percentage of participants				
number (not applicable)				
Total hypoglycemic events	77.0	79.8		
Nocturnal hypoglycemic events	48.9	59.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HbA1C Equal or Less Than 6.5% and Less Than 7.0 % and Without Nocturnal Hypoglycemia

End point title	Percentage of Participants With HbA1C Equal or Less Than 6.5% and Less Than 7.0 % and Without Nocturnal Hypoglycemia
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End point description:

The percentage of participants with HbA1C \leq 6.5% or $<$ 7.0% without nocturnal hypoglycemia is presented. Percentage was calculated by dividing the number of participants with the indicated HbA1c values over the total number of participants and multiplying by 100.

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline HbA1c measurement. Missing endpoints were imputed with the LOCF method, using only post-baseline data.

End point type	Secondary
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End point timeframe:

Up to 52 weeks

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	989	523		
Units: percentage of participants				
number (not applicable)				
HbA1c \leq 6.5%	17.5	8.6		
HbA1c $<$ 7.0%	26.2	15.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Equal or Above 2- and 3-fold ULN for Alanine Transaminase/Serum Glutamic Pyruvic Transaminase (ALT/SGPT) and Aspartate Transaminase/Serum Glutamic Oxaloacetic Transaminase (AST/SGOT)

End point title	Percentage of Participants With Equal or Above 2- and 3-fold ULN for Alanine Transaminase/Serum Glutamic Pyruvic Transaminase (ALT/SGPT) and Aspartate Transaminase/Serum Glutamic Oxaloacetic Transaminase (AST/SGOT)
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End point description:

The percentage of participants was calculated by dividing the number of participants equal or above 2- or 3-fold ULN for ALT/SGPT or AST/SGOT by the total number of participants analyzed, multiplied by 100.

End point type	Secondary
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End point timeframe:

Up to 52 weeks

Analysis Population Description: All participants who were randomized, received at least 1 dose of study drug, and had evaluable post-baseline liver enzyme data.

End point values	LY2605541	Glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	990	524		
Units: percentage of participants				
number (not applicable)				
≥2-fold ULN for ALT	6.5	4.0		
≥3-fold ULN for ALT	1.9	0.6		
≥2-fold ULN for AST	3.6	1.5		
≥3-fold ULN for AST	1.0	0.4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Analysis Period 2 (AP2)

Adverse event reporting additional description:

I2R-MC-BIAJ

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Glargine
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Reporting group description: -

Reporting group title	LY2605541
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Reporting group description: -

Serious adverse events	Glargine	LY2605541	
Total subjects affected by serious adverse events			
subjects affected / exposed	73 / 535 (13.64%)	105 / 1003 (10.47%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
adenocarcinoma of colon			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
benign gastric neoplasm			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder transitional cell carcinoma alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast cancer alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
endometrial adenocarcinoma alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive ductal breast carcinoma alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lentigo maligna alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

lung adenocarcinoma alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung neoplasm malignant alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant melanoma alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to salivary gland alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-small cell lung cancer alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal cancer metastatic alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
pancreatic carcinoma alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer metastatic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal adenoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

squamous cell carcinoma of the tongue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transitional cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
aortic stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertension			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoperfusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
iliac artery occlusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
shock			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Surgical and medical procedures			
coronary artery bypass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
glossectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
radical neck dissection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
death			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
device occlusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
sarcoidosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic floor muscle weakness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pharyngeal cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleuritic pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary mass			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
weight increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clavicle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus injury			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
scapula fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thoracic vertebral fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina pectoris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina unstable			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic valve stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial flutter			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

atrioventricular block alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
atrioventricular block complete alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
atrioventricular block second degree alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
bradycardia alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
cardiac arrest alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
cardiac failure alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
cardiac failure congestive alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac tamponade			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertensive heart disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
myocardial ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

right ventricular failure alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 535 (0.19%) 0 / 1 0 / 0	0 / 1003 (0.00%) 0 / 0 0 / 0	
sinus tachycardia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 535 (0.00%) 0 / 0 0 / 0	1 / 1003 (0.10%) 0 / 1 0 / 0	
supraventricular tachycardia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 535 (0.19%) 0 / 1 0 / 0	0 / 1003 (0.00%) 0 / 0 0 / 0	
ventricular arrhythmia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 535 (0.00%) 0 / 0 0 / 0	1 / 1003 (0.10%) 0 / 1 0 / 0	
wolff-parkinson-white syndrome alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 535 (0.00%) 0 / 0 0 / 0	1 / 1003 (0.10%) 0 / 1 0 / 0	
Nervous system disorders autonomic neuropathy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all cerebral ischaemia alternative dictionary used: MedDRA 16.0	0 / 535 (0.00%) 0 / 0 0 / 0	1 / 1003 (0.10%) 0 / 2 0 / 0	

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervicobrachial syndrome alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
complex partial seizures alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic neuropathy alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhage intracranial alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
hemiparesis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

<p>ischaemic cerebral infarction</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 535 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>1 / 1003 (0.10%)</p> <p>0 / 1</p> <p>0 / 0</p>	
<p>ischaemic stroke</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 535 (0.19%)</p> <p>0 / 1</p> <p>0 / 0</p>	<p>2 / 1003 (0.20%)</p> <p>0 / 2</p> <p>0 / 0</p>	
<p>lacunar infarction</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 535 (0.19%)</p> <p>0 / 1</p> <p>0 / 0</p>	<p>0 / 1003 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	
<p>migraine</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 535 (0.19%)</p> <p>0 / 2</p> <p>0 / 0</p>	<p>0 / 1003 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	
<p>syncope</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 535 (0.19%)</p> <p>1 / 1</p> <p>0 / 0</p>	<p>0 / 1003 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	
<p>transient ischaemic attack</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>3 / 535 (0.56%)</p> <p>0 / 4</p> <p>0 / 0</p>	<p>2 / 1003 (0.20%)</p> <p>0 / 2</p> <p>0 / 0</p>	
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vestibular ataxia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitreous haemorrhage			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ascites			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric fistula			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroduodenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis eosinophilic			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroesophageal reflux disease alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal haemorrhage alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine perforation alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophagitis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis acute alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper gastrointestinal haemorrhage alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

vomiting alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 535 (0.00%) 0 / 0 0 / 0	1 / 1003 (0.10%) 0 / 1 0 / 0	
Hepatobiliary disorders cholangitis acute alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 535 (0.19%) 0 / 1 0 / 0	0 / 1003 (0.00%) 0 / 0 0 / 0	
cholecystitis acute alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 535 (0.19%) 0 / 1 0 / 0	1 / 1003 (0.10%) 0 / 1 0 / 0	
cholelithiasis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 535 (0.00%) 0 / 0 0 / 0	4 / 1003 (0.40%) 0 / 5 0 / 0	
hepatic cirrhosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 535 (0.00%) 0 / 0 0 / 0	1 / 1003 (0.10%) 0 / 1 0 / 0	
hydrocholecystis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 535 (0.19%) 0 / 1 0 / 0	0 / 1003 (0.00%) 0 / 0 0 / 0	
Skin and subcutaneous tissue disorders angioedema alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urticaria chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vasculitic rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar spinal stenosis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal column stenosis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal osteoarthritis alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations abdominal abscess alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchopneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis infective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
escherichia bacteraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder empyema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
necrotising fasciitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
osteomyelitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
sepsis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 535 (0.75%)	7 / 1003 (0.70%)	
occurrences causally related to treatment / all	3 / 4	6 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypokalaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypophagia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Glargine	LY2605541	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	390 / 535 (72.90%)	733 / 1003 (73.08%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acrochordon			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
adenoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
adrenal adenoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)	
occurrences (all)	0	3	
benign breast neoplasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
benign neoplasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	

benign neoplasm of thyroid gland		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
melanocytic naevus		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
neoplasm prostate		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
neoplasm skin		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
prostate cancer		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
seborrhoeic keratosis		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
skin papilloma		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
squamous cell carcinoma		
alternative dictionary used:		
MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
thyroid neoplasm		
alternative dictionary used:		
MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tracheal neoplasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
tumour pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
angiopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
aortic arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
aortic stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
arteriosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
blood pressure inadequately controlled			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
deep vein thrombosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
diabetic microangiopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
essential hypertension		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	2
flushing		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
haematoma		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
hot flush		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
hypertension		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	12 / 535 (2.24%)	41 / 1003 (4.09%)
occurrences (all)	12	43
hypotension		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)
occurrences (all)	4	2

intermittent claudication		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
intra-abdominal haematoma		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
ischaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
lymphoedema		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
orthostatic hypotension		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
peripheral arterial occlusive disease		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
peripheral vascular disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
thrombophlebitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
varicose vein		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
venous insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
abdominoplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
angioplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
aortic valve replacement			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
apicectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
atherectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
blepharoplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
bone lesion excision			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
cardiac pacemaker insertion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
carpal tunnel decompression		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
cataract operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)
occurrences (all)	6	4
cholecystectomy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)
occurrences (all)	4	3
colectomy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
coronary angioplasty		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
coronary arterial stent insertion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	4	1
coronary artery bypass		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3

cyst removal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dental care		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
dental disorder prophylaxis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dental implantation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dental operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
endodontic procedure		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
explorative laparotomy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
eye laser surgery		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
finger repair operation		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
gastric operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gastric polypectomy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
haemorrhoid operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
hip arthroplasty		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
hysterectomy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
knee arthroplasty		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
laryngeal operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
limb operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

lithotripsy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
mammoplasty		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
micrographic skin surgery		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
mitral valve replacement		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
mole excision		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
nail operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
oral surgery		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
percutaneous coronary intervention		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
perineoplasty		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
peripheral nerve decompression		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pneumonectomy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
salpingo-oophorectomy bilateral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
sclerotherapy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
skin graft		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
skin neoplasm excision		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
spermatocele excision		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
stent placement		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

stent removal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tendon operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
tendon sheath incision		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
toe operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tooth extraction		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	11 / 1003 (1.10%)
occurrences (all)	4	12
tooth repair		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
ureteral stent insertion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
varicose vein operation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
vitrectomy		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 2	
General disorders and administration site conditions			
application site pruritus alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	2 / 535 (0.37%) 2	0 / 1003 (0.00%) 0	
asthenia alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	7 / 535 (1.31%) 8	8 / 1003 (0.80%) 9	
axillary pain alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
chest discomfort alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
chest pain alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	9 / 1003 (0.90%) 10	
chills alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	5 / 1003 (0.50%) 6	
chronic fatigue syndrome alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
cyst alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
discomfort		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	4
drug intolerance		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
early satiety		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
fat tissue increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
fatigue		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	14 / 535 (2.62%)	35 / 1003 (3.49%)
occurrences (all)	15	38
feeling abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
feeling jittery		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
feeling of body temperature change		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

hunger		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
hyperpyrexia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
impaired healing		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
inflammation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
influenza like illness		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	9 / 1003 (0.90%)
occurrences (all)	1	9
infusion site bruising		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
injection site hypertrophy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	5
injection site induration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
injection site inflammation		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
injection site oedema		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
injection site pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
injection site pruritus		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
injection site rash		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
injection site reaction		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
injection site swelling		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
irritability		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
local swelling		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

malaise		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	4 / 1003 (0.40%)
occurrences (all)	5	6
nodule		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
non-cardiac chest pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
oedema		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	8 / 1003 (0.80%)
occurrences (all)	3	8
oedema peripheral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	16 / 535 (2.99%)	29 / 1003 (2.89%)
occurrences (all)	18	34
pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	12 / 1003 (1.20%)
occurrences (all)	3	14
puncture site haemorrhage		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
pyrexia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	5 / 535 (0.93%)	17 / 1003 (1.69%)
occurrences (all)	5	18
spinal pain		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)	
occurrences (all)	2	4	
therapeutic response unexpected			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	1	3	
thirst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vessel puncture site bruise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
allergy to arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
allergy to arthropod sting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
contrast media allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
food allergy			
alternative dictionary used: MedDRA 16.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 535 (0.00%)</p> <p>0</p>	<p>1 / 1003 (0.10%)</p> <p>1</p>	
<p>hypersensitivity</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>3 / 1003 (0.30%)</p> <p>3</p>	
<p>reaction to food additive</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>seasonal allergy</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>7 / 535 (1.31%)</p> <p>7</p>	<p>7 / 1003 (0.70%)</p> <p>9</p>	
<p>Reproductive system and breast disorders</p> <p>benign prostatic hyperplasia</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 535 (0.56%)</p> <p>3</p>	<p>4 / 1003 (0.40%)</p> <p>4</p>	
<p>breast mass</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>dysmenorrhoea</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 535 (0.37%)</p> <p>2</p>	<p>2 / 1003 (0.20%)</p> <p>6</p>	
<p>endometrial hypertrophy</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>epididymal cyst</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
epididymitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
erectile dysfunction		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)
occurrences (all)	0	6
menstruation irregular		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
metrorrhagia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
orchitis noninfective		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
pelvic pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
penis disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
postmenopausal haemorrhage		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

premenstrual syndrome alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
prostatitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 535 (0.56%) 5	2 / 1003 (0.20%) 2	
prostatomegaly alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
scrotal mass alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
testicular pain alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	3 / 1003 (0.30%) 5	
vaginal discharge alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	2 / 1003 (0.20%) 2	
vulvovaginal pruritus alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 535 (0.37%) 2	0 / 1003 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders allergic sinusitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
apnoeic attack alternative dictionary used:			

MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
asthma		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)
occurrences (all)	3	11
atelectasis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
chronic obstructive pulmonary disease		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)
occurrences (all)	1	4
cough		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	18 / 535 (3.36%)	44 / 1003 (4.39%)
occurrences (all)	22	52
dysphonia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
dyspnoea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	15 / 1003 (1.50%)
occurrences (all)	2	16
dyspnoea exertional		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3
emphysema		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
epistaxis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	4	3
lung disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nasal congestion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	8 / 1003 (0.80%)
occurrences (all)	4	8
nasal inflammation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nasal septum deviation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nasal septum perforation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
oropharyngeal pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	19 / 535 (3.55%)	34 / 1003 (3.39%)
occurrences (all)	21	40
orthopnoea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

paranasal sinus hypersecretion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
pleural effusion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
pleurisy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pneumonitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
productive cough		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	7 / 1003 (0.70%)
occurrences (all)	0	8
pulmonary congestion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pulmonary fibrosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pulmonary hypertension		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
respiratory disorder		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	6 / 535 (1.12%)	2 / 1003 (0.20%)
occurrences (all)	6	2
respiratory distress		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
respiratory tract congestion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	7 / 1003 (0.70%)
occurrences (all)	1	7
rhinitis allergic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)
occurrences (all)	3	6
rhinitis seasonal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
rhinorrhoea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)
occurrences (all)	2	4
sinus congestion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)
occurrences (all)	5	6
sleep apnoea syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	3 / 1003 (0.30%)
occurrences (all)	6	3
sneezing		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

throat irritation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	3 / 1003 (0.30%) 3	
tonsillar inflammation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
upper respiratory tract congestion alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
upper respiratory tract inflammation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
upper-airway cough syndrome alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
wheezing alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 535 (0.37%) 2	3 / 1003 (0.30%) 4	
Psychiatric disorders abnormal behaviour alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
adjustment disorder alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
affect lability alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
agitation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
anxiety		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	7 / 535 (1.31%)	11 / 1003 (1.10%)
occurrences (all)	8	11
confusional state		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
daydreaming		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
depressed mood		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
depression		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	10 / 1003 (1.00%)
occurrences (all)	6	10
disorientation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
drug abuse		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

fear of eating		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
insomnia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	11 / 535 (2.06%)	15 / 1003 (1.50%)
occurrences (all)	11	16
libido decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
mental disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
mental disorder due to a general medical condition		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nervousness		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
nightmare		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
obsessive-compulsive disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
panic attack		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
personality disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
phonophobia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
sleep disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)	
occurrences (all)	2	4	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	24 / 1003 (2.39%)	
occurrences (all)	3	25	
amino acid level increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
angiogram			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
antinuclear antibody positive		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
arteriogram coronary		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
aspartate aminotransferase increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	15 / 1003 (1.50%)
occurrences (all)	2	15
blood alkaline phosphatase increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
blood bicarbonate increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
blood bilirubin increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
blood calcium increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
blood creatine increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

blood creatine phosphokinase increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	12 / 535 (2.24%) 12	9 / 1003 (0.90%) 9
blood creatinine increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	2 / 1003 (0.20%) 2
blood glucose increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1
blood iron decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1
blood lactate dehydrogenase increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0
blood magnesium decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0
blood potassium decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0
blood potassium increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0
blood pressure increased alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	3	3
blood testosterone decreased alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	1 / 1003 (0.10%)
occurrences (all)	4	1
blood triglycerides increased alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	8 / 1003 (0.80%)
occurrences (all)	0	8
blood urea increased alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
blood uric acid increased alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
blood urine present alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
bronchoscopy alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
catheterisation cardiac alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
colonoscopy alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1

electrocardiogram p wave abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
electrocardiogram st-t segment abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
electrocardiogram t wave inversion alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
electrocardiogram abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
electroencephalogram abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
eosinophil count increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
gamma-glutamyltransferase increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
gastric ph decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
haematocrit increased alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
haemoglobin increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
heart rate irregular		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
helicobacter test positive		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
hepatic enzyme abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
hepatic enzyme increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3
hepatitis b antibody positive		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
human chorionic gonadotropin abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
human chorionic gonadotropin increased		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
left ventricular end-diastolic pressure increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
liver function test abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)
occurrences (all)	2	4
lymphocyte morphology abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
mean cell haemoglobin decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
mean cell volume decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
oesophagogastroduodenoscopy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
platelet count decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
prostatic specific antigen increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	3

protein urine		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
protein urine present		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
qrs axis abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
serum ferritin decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
vitamin d decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
vitamin d increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
waist circumference increased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
weight decreased		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
weight increased		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed occurrences (all)	18 / 535 (3.36%) 18	26 / 1003 (2.59%) 28	
white blood cell count increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
white blood cells urine positive alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	2 / 1003 (0.20%) 2	
Injury, poisoning and procedural complications			
anaemia postoperative alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
animal bite alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
ankle fracture alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
arthropod bite alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	6 / 535 (1.12%) 7	11 / 1003 (1.10%) 11	
arthropod sting alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	2 / 1003 (0.20%) 2	
asbestosis alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
avulsion fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
back injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	3	1
bone contusion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)
occurrences (all)	3	0
burns first degree		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
chest crushing		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
chest injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
contusion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	17 / 1003 (1.69%)
occurrences (all)	9	20
epicondylitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

excoriation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)
occurrences (all)	1	8
exposure to toxic agent		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
facial bones fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
fall		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)
occurrences (all)	3	12
fibula fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
foot fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	5 / 1003 (0.50%)
occurrences (all)	2	6
foreign body		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
foreign body in eye		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
hand fracture		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	3
head injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
heat exhaustion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
joint dislocation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)
occurrences (all)	4	4
joint injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	7 / 535 (1.31%)	2 / 1003 (0.20%)
occurrences (all)	7	2
laceration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)
occurrences (all)	3	9
ligament sprain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	9 / 535 (1.68%)	6 / 1003 (0.60%)
occurrences (all)	9	6
limb injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)
occurrences (all)	2	5
liver contusion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
muscle contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
muscle rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	10 / 1003 (1.00%)	
occurrences (all)	2	10	
nail avulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
nail injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
patella fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
pelvic fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
periorbital haematoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
post procedural complication		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
post-traumatic neck syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
postoperative respiratory failure		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
procedural pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	3	1
radius fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
rib fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
scratch		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
skeletal injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2

soft tissue injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
spinal compression fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
spinal fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
stab wound		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tendon injury		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tendon rupture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
thermal burn		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	3	1
traumatic fracture		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
upper limb fracture		
alternative dictionary used: MedDRA 16.0		

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 535 (0.00%)</p> <p>0</p>	<p>2 / 1003 (0.20%)</p> <p>2</p>	
<p>vaccination complication</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>wound</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 535 (0.56%)</p> <p>3</p>	<p>3 / 1003 (0.30%)</p> <p>3</p>	
<p>Congenital, familial and genetic disorders</p> <p>atrial septal defect</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>corneal dystrophy</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 535 (0.00%)</p> <p>0</p>	<p>1 / 1003 (0.10%)</p> <p>1</p>	
<p>kidney duplex</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>phimosis</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>1 / 1003 (0.10%)</p> <p>1</p>	
<p>type v hyperlipidaemia</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 535 (0.00%)</p> <p>0</p>	<p>2 / 1003 (0.20%)</p> <p>2</p>	
<p>Cardiac disorders</p> <p>angina pectoris</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
aortic valve incompetence		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
arrhythmia supraventricular		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
atrial fibrillation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	3 / 1003 (0.30%)
occurrences (all)	3	4
atrioventricular block first degree		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
bradycardia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)
occurrences (all)	2	4
bundle branch block left		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
bundle branch block right		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)
occurrences (all)	3	0
cardiac aneurysm		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

cardiac arrest		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
cardiac failure		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	3
cardiac failure congestive		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	0 / 1003 (0.00%)
occurrences (all)	5	0
cardiomegaly		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
cardiomyopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
conduction disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
coronary artery disease		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	3 / 1003 (0.30%)
occurrences (all)	4	3
coronary ostial stenosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
diastolic dysfunction		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
extrasystoles		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
ischaemic cardiomyopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
left ventricular failure		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
left ventricular hypertrophy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
mitral valve incompetence		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
myocardial infarction		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
myocardial ischaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
palpitations		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	5 / 535 (0.93%)	7 / 1003 (0.70%)
occurrences (all)	7	8

pericardial effusion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
prinzmetal angina		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pulmonary valve incompetence		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
silent myocardial infarction		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
sinus bradycardia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
sinus tachycardia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
supraventricular extrasystoles		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
tachyarrhythmia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
tachycardia		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	2	4	
tricuspid valve incompetence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
ventricular arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
ventricular extrasystoles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)	
occurrences (all)	0	4	
ventricular hypertrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
ventricular tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
altered state of consciousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
amnesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	2
balance disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)
occurrences (all)	1	4
carpal tunnel syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)
occurrences (all)	3	7
cerebrovascular accident		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
cervical root pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
cervicobrachial syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
convulsion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
diabetic neuropathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	9 / 1003 (0.90%)
occurrences (all)	6	9
disturbance in attention		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2

dizziness		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	17 / 535 (3.18%)	32 / 1003 (3.19%)
occurrences (all)	29	36
dizziness postural		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)
occurrences (all)	3	0
dysgeusia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3
headache		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	37 / 535 (6.92%)	85 / 1003 (8.47%)
occurrences (all)	72	134
hemiparesis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
hypoesthesia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	14 / 1003 (1.40%)
occurrences (all)	2	15
lacunar infarction		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
lethargy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
memory impairment		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
meralgia paraesthetica		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
migraine		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)
occurrences (all)	4	15
nerve compression		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3
neuralgia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
neuropathy peripheral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)
occurrences (all)	6	6
paraesthesia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	8 / 535 (1.50%)	12 / 1003 (1.20%)
occurrences (all)	10	13
parkinsonism		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
partial seizures		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

post-traumatic headache		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
presyncope		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
radiculitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
radiculopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
restless legs syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
sciatica		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	9 / 535 (1.68%)	6 / 1003 (0.60%)
occurrences (all)	9	7
sinus headache		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
somnolence		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
spinal cord disorder		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)	
occurrences (all)	0	5	
transient ischaemic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tremor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
viith nerve paralysis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)	
occurrences (all)	1	5	
white matter lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 535 (0.93%)	14 / 1003 (1.40%)	
occurrences (all)	5	17	
anaemia macrocytic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
coagulopathy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
eosinophilia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
hypersplenism		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
iron deficiency anaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
leukocytosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
lymphadenitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
lymphadenopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
lymphocytosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pernicious anaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

splenomegaly alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	2 / 1003 (0.20%) 2	
Ear and labyrinth disorders			
cerumen impaction alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
deafness alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	2 / 1003 (0.20%) 2	
deafness bilateral alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
ear discomfort alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 2	0 / 1003 (0.00%) 0	
ear pain alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	8 / 535 (1.50%) 10	7 / 1003 (0.70%) 8	
eustachian tube disorder alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
hypoacusis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 535 (0.37%) 2	1 / 1003 (0.10%) 1	
otosclerosis alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tympanic membrane perforation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	12 / 1003 (1.20%)	
occurrences (all)	8	13	
vertigo positional			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vestibular disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Eye disorders			
arcus lipoides			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
asthenopia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
blepharitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
blepharospasm		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
blindness unilateral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
cataract		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	10 / 1003 (1.00%)
occurrences (all)	1	11
chalazion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
conjunctivitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)
occurrences (all)	3	5
conjunctivitis allergic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
dacryostenosis acquired		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
diabetic retinopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	6 / 1003 (0.60%)
occurrences (all)	1	6

diplopia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
dry eye		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
eye allergy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
eye discharge		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
eye haemorrhage		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
eye pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
eye pruritus		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
eye swelling		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
glaucoma		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
iris neovascularisation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
iritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
keratitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
macular oedema		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
maculopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
ocular hyperaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
ocular hypertension		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
open angle glaucoma		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0

optic ischaemic neuropathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
photophobia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
retinal exudates		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
retinopathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
sudden visual loss		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	3
vision blurred		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	8 / 1003 (0.80%)
occurrences (all)	1	9
visual acuity reduced		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
visual impairment		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
vitreous floaters		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
vitreous haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	9 / 1003 (0.90%)	
occurrences (all)	0	9	
abdominal distension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	8 / 1003 (0.80%)	
occurrences (all)	2	8	
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 535 (1.87%)	13 / 1003 (1.30%)	
occurrences (all)	12	14	
abdominal pain lower			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)	
occurrences (all)	1	2	
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 535 (1.12%)	19 / 1003 (1.89%)	
occurrences (all)	6	24	
abnormal faeces			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
anal fistula			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
aphthous stomatitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
ascites		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
barrett's oesophagus		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
change of bowel habit		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	2	1
chapped lips		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
colitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	2	3
colitis psychogenic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
constipation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	7 / 535 (1.31%)	6 / 1003 (0.60%)
occurrences (all)	7	6

dental caries		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
diarrhoea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	38 / 535 (7.10%)	57 / 1003 (5.68%)
occurrences (all)	52	81
diverticulum		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
dry mouth		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)
occurrences (all)	1	4
duodenal ulcer		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
duodenitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dyspepsia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	13 / 1003 (1.30%)
occurrences (all)	7	15
dysphagia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
epigastric discomfort		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
eructation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
faecaloma		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
flatulence		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)
occurrences (all)	3	6
food poisoning		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)
occurrences (all)	5	6
gastric mucosa erythema		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gastric polyps		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gastric ulcer		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
gastritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)
occurrences (all)	3	9

gastritis atrophic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
gastritis erosive		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
gastrointestinal pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gastrooesophageal reflux disease		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	8 / 1003 (0.80%)
occurrences (all)	4	8
gingival disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gingival inflammation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gingival pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
haematochezia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
haemorrhoids		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
hiatus hernia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
hyperchlorhydria		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	13
inguinal hernia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	2	1
irritable bowel syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
large intestine polyp		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
lip swelling		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
mouth ulceration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
nausea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	18 / 535 (3.36%)	37 / 1003 (3.69%)
occurrences (all)	30	51

oesophageal ulcer		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
oesophagitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
oral disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
oral pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pancreatitis chronic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
paraesthesia oral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
periodontal disease		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
rectal polyp		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
stomatitis		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
tongue disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
toothache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	22 / 1003 (2.19%)	
occurrences (all)	3	27	
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 535 (2.99%)	35 / 1003 (3.49%)	
occurrences (all)	21	49	
Hepatobiliary disorders			
biliary colic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)	
occurrences (all)	2	3	
biliary dyskinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
cholecystitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)	
occurrences (all)	3	4	
hepatic steatosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	7 / 1003 (0.70%)	
occurrences (all)	1	7	
hepatomegaly			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hypertransaminasaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
post cholecystectomy syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
actinic keratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
alopecia areata			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
blister		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
blood blister		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
cold sweat		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)
occurrences (all)	4	0
cutaneous sarcoidosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dandruff		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
decubitus ulcer		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dermal cyst		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
dermatitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)
occurrences (all)	3	9

dermatitis allergic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	3 / 1003 (0.30%)
occurrences (all)	3	3
dermatitis atopic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
dermatitis contact		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
diabetic foot		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
drug eruption		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
dry skin		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)
occurrences (all)	0	6
eczema		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	4 / 1003 (0.40%)
occurrences (all)	4	4
eczema nummular		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
erythema		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)
occurrences (all)	1	7
hand dermatitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
hidradenitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
hyperhidrosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	2 / 1003 (0.20%)
occurrences (all)	4	2
hyperkeratosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
ingrowing nail		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	3	2
ingrown hair		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
lentigo		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
lichen sclerosus		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1

lipodystrophy acquired		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
lipohypertrophy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	21 / 1003 (2.09%)
occurrences (all)	2	22
macule		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nail disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
neurodermatitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
night sweats		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
panniculitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
papule		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pemphigus		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pigmentation disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
precancerous skin lesion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
pruritus		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	7 / 1003 (0.70%)
occurrences (all)	4	7
pruritus allergic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pruritus generalised		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
psoriasis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	5	3
rash		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	7 / 535 (1.31%)	24 / 1003 (2.39%)
occurrences (all)	8	27
rash erythematous		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1

rash generalised		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
rash macular		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
rash pruritic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
rosacea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
sebaceous hyperplasia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
seborrhoea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
skin burning sensation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
skin discolouration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
skin exfoliation		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
skin fissures		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
skin hypertrophy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
skin induration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
skin irritation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
skin lesion		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
skin mass		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
skin odour abnormal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
skin ulcer		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	4 / 1003 (0.40%)
occurrences (all)	3	5

telangiectasia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
urticaria alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 535 (0.56%) 3	3 / 1003 (0.30%) 4	
Renal and urinary disorders bladder diverticulum alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
bladder irritation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
bladder prolapse alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
diabetic nephropathy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
dysuria alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	5 / 1003 (0.50%) 5	
haematuria alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	1 / 1003 (0.10%) 1	
hypertonic bladder alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
micturition disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
micturition urgency		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nephritic syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
nephrolithiasis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	8 / 535 (1.50%)	8 / 1003 (0.80%)
occurrences (all)	9	10
nephropathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nocturia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
pollakiuria		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
proteinuria		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4

renal colic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
renal cyst		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	4	1
renal failure		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
renal failure chronic		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
renal impairment		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
renal pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
urinary hesitation		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
urinary incontinence		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
urinary tract disorder		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
urinary tract obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
urinary tract pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
urine flow decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
urine odour abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
hyperthyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)	
occurrences (all)	3	5	
toxic nodular goitre			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	20 / 535 (3.74%)	52 / 1003 (5.18%)	
occurrences (all)	47	68	
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	8 / 1003 (0.80%)	
occurrences (all)	4	9	
arthropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)	
occurrences (all)	2	0	
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	36 / 535 (6.73%)	70 / 1003 (6.98%)	
occurrences (all)	47	89	
bone loss			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
bone pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
bursitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	5 / 1003 (0.50%)	
occurrences (all)	2	5	
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
chondropathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
costochondritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	2	1
facet joint syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
fibromyalgia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
flank pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)
occurrences (all)	3	0
gouty arthritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
intervertebral disc degeneration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
intervertebral disc disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3

<p>intervertebral disc protrusion</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 535 (0.37%)</p> <p>2</p>	<p>2 / 1003 (0.20%)</p> <p>2</p>	
<p>joint stiffness</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>joint swelling</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>3 / 1003 (0.30%)</p> <p>3</p>	
<p>ligament pain</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>0 / 1003 (0.00%)</p> <p>0</p>	
<p>metatarsalgia</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 535 (0.00%)</p> <p>0</p>	<p>1 / 1003 (0.10%)</p> <p>1</p>	
<p>muscle contracture</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 535 (0.19%)</p> <p>1</p>	<p>1 / 1003 (0.10%)</p> <p>1</p>	
<p>muscle spasms</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>9 / 535 (1.68%)</p> <p>9</p>	<p>21 / 1003 (2.09%)</p> <p>21</p>	
<p>muscle swelling</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 535 (0.00%)</p> <p>0</p>	<p>1 / 1003 (0.10%)</p> <p>1</p>	
<p>muscular weakness</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
musculoskeletal chest pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)
occurrences (all)	1	5
musculoskeletal pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	16 / 535 (2.99%)	22 / 1003 (2.19%)
occurrences (all)	16	24
musculoskeletal stiffness		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)
occurrences (all)	4	2
myalgia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	18 / 1003 (1.79%)
occurrences (all)	6	26
myosclerosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
myositis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
neck pain		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)
occurrences (all)	4	7
neuropathic arthropathy		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	3	0

osteoarthritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	10 / 535 (1.87%)	14 / 1003 (1.40%)
occurrences (all)	11	15
osteochondrosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
pain in extremity		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	25 / 535 (4.67%)	42 / 1003 (4.19%)
occurrences (all)	36	50
pain in jaw		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
periarthritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	2 / 1003 (0.20%)
occurrences (all)	2	2
plantar fasciitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
polyarthritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
rheumatoid arthritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	3
rotator cuff syndrome		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)
occurrences (all)	1	6
scoliosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
spinal column stenosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
spinal disorder		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
spinal osteoarthritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)
occurrences (all)	3	5
spondylitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
synovial cyst		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
temporomandibular joint syndrome		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tendonitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	5 / 1003 (0.50%)
occurrences (all)	2	5

trigger finger alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	2 / 1003 (0.20%) 2	
Infections and infestations			
abscess alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
abscess jaw alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
abscess limb alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	3 / 1003 (0.30%) 4	
abscess neck alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 535 (0.00%) 0	1 / 1003 (0.10%) 1	
acne pustular alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 1	0 / 1003 (0.00%) 0	
acute sinusitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 535 (0.37%) 2	4 / 1003 (0.40%) 4	
acute tonsillitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 535 (0.19%) 2	4 / 1003 (0.40%) 4	
anal abscess alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
body tinea		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
breast cellulitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
bronchiolitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
bronchitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	24 / 535 (4.49%)	52 / 1003 (5.18%)
occurrences (all)	26	60
bronchitis bacterial		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
bronchitis viral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
bronchopneumonia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
campylobacter infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1

candidiasis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
carbuncle		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
cellulitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	9 / 1003 (0.90%)
occurrences (all)	6	9
chronic hepatitis b		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
chronic sinusitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
conjunctivitis bacterial		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
conjunctivitis viral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
cystitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	4 / 535 (0.75%)	6 / 1003 (0.60%)
occurrences (all)	4	12
diverticulitis		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	6 / 1003 (0.60%)
occurrences (all)	1	6
ear infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)
occurrences (all)	4	10
enterovirus infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
erysipelas		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
eye infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
eye infection bacterial		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
folliculitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
fungus infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	5 / 1003 (0.50%)
occurrences (all)	2	5
fungus skin infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1

furuncle		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	4 / 1003 (0.40%)
occurrences (all)	0	4
gangrene		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gardnerella infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
gastroenteritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	8 / 535 (1.50%)	13 / 1003 (1.30%)
occurrences (all)	8	14
gastroenteritis viral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	8 / 535 (1.50%)	15 / 1003 (1.50%)
occurrences (all)	8	20
gastrointestinal viral infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	3	1
genital infection fungal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
gingival infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
gingivitis		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
helicobacter infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	2	3
hepatitis c		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
hepatitis e		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
herpes simplex		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
herpes virus infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
herpes zoster		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	7 / 1003 (0.70%)
occurrences (all)	6	8
hordeolum		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
incision site infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1

infected dermal cyst		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	2
influenza		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	28 / 535 (5.23%)	59 / 1003 (5.88%)
occurrences (all)	35	68
injection site cellulitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
kidney infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
labyrinthitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
laryngitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)
occurrences (all)	0	5
lobar pneumonia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
localised infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	5 / 535 (0.93%)	4 / 1003 (0.40%)
occurrences (all)	5	4
lower respiratory tract infection		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	5 / 535 (0.93%)	11 / 1003 (1.10%)
occurrences (all)	5	14
measles		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
nail infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
nasopharyngitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	82 / 535 (15.33%)	141 / 1003 (14.06%)
occurrences (all)	122	196
nematodiasis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
onychomycosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	6 / 1003 (0.60%)
occurrences (all)	2	6
oral candidiasis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
oral herpes		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	2 / 1003 (0.20%)
occurrences (all)	4	3
otitis externa		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)
occurrences (all)	1	4

otitis media		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)
occurrences (all)	3	5
otitis media acute		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
paronychia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	2	0
parotitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
penile infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
periodontitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
pharyngitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	5 / 535 (0.93%)	14 / 1003 (1.40%)
occurrences (all)	7	18
pharyngitis streptococcal		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	2
pharyngotonsillitis		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	3	1
pilonidal cyst		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pneumonia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	10 / 1003 (1.00%)
occurrences (all)	2	11
post procedural infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
prostate infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pulpitis dental		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pyelonephritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
pyelonephritis acute		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
respiratory tract infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)
occurrences (all)	3	6

respiratory tract infection viral		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)
occurrences (all)	2	1
rhinitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	8 / 535 (1.50%)	5 / 1003 (0.50%)
occurrences (all)	10	6
rhinovirus infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	4
sialoadenitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
sinusitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	16 / 535 (2.99%)	38 / 1003 (3.79%)
occurrences (all)	17	51
sinusitis bacterial		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
skin candida		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
small intestinal bacterial overgrowth		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
subcutaneous abscess		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
tinea cruris		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tinea infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
tinea pedis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	5 / 1003 (0.50%)
occurrences (all)	0	6
tinea versicolour		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
tonsillitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	3 / 1003 (0.30%)
occurrences (all)	3	3
tooth abscess		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	12 / 1003 (1.20%)
occurrences (all)	2	13
tooth infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	9 / 1003 (0.90%)
occurrences (all)	3	10
tracheitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1

tracheobronchitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
tuberculosis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
upper respiratory tract infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	33 / 535 (6.17%)	83 / 1003 (8.28%)
occurrences (all)	48	119
urethritis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
urinary tract infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	22 / 535 (4.11%)	47 / 1003 (4.69%)
occurrences (all)	28	57
viraemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
viral infection		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	6 / 535 (1.12%)	12 / 1003 (1.20%)
occurrences (all)	7	12
viral rhinitis		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)
occurrences (all)	0	1
viral tonsillitis		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	4 / 1003 (0.40%)	
occurrences (all)	1	4	
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)	
occurrences (all)	1	1	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)	
occurrences (all)	3	1	
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
yersinia infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	1 / 1003 (0.10%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
abnormal loss of weight			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	1 / 1003 (0.10%)	
occurrences (all)	2	1	
abnormal weight gain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 535 (0.37%)	4 / 1003 (0.40%)	
occurrences (all)	3	4	
decreased appetite			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 535 (0.56%)	5 / 1003 (0.50%)
occurrences (all)	3	5
dehydration		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)
occurrences (all)	0	2
dyslipidaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	5 / 535 (0.93%)	5 / 1003 (0.50%)
occurrences (all)	6	5
fluid retention		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	2 / 1003 (0.20%)
occurrences (all)	1	2
food craving		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
gout		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	8 / 1003 (0.80%)
occurrences (all)	1	9
hypercholesterolaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	1 / 1003 (0.10%)
occurrences (all)	3	1
hyperglycaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
hyperkalaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	3 / 535 (0.56%)	0 / 1003 (0.00%)
occurrences (all)	4	0

hyperlipidaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
hypertriglyceridaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)
occurrences (all)	0	6
hyperuricaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	3 / 1003 (0.30%)
occurrences (all)	1	3
hypoalbuminaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)
occurrences (all)	1	0
hypokalaemia		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	3 / 1003 (0.30%)
occurrences (all)	0	3
increased appetite		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	0 / 535 (0.00%)	6 / 1003 (0.60%)
occurrences (all)	0	6
iron deficiency		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	2 / 535 (0.37%)	0 / 1003 (0.00%)
occurrences (all)	2	0
obesity		
alternative dictionary used: MedDRA 16.0		
subjects affected / exposed	1 / 535 (0.19%)	1 / 1003 (0.10%)
occurrences (all)	1	1
type 2 diabetes mellitus		
alternative dictionary used: MedDRA 16.0		

subjects affected / exposed	1 / 535 (0.19%)	0 / 1003 (0.00%)	
occurrences (all)	1	0	
vitamin b12 deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 535 (0.00%)	2 / 1003 (0.20%)	
occurrences (all)	0	2	
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 535 (0.56%)	6 / 1003 (0.60%)	
occurrences (all)	3	6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported